SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PERMIXON 160 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Lipidosterolic extract of Serenoa repens 160mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Capsule

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of moderate micturition troubles related to benign hypertrophy of prostate in adult men.

4.2 Dosage and method of administration

2 capsules a day, at mealtimes.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

In accordance with the routine monitoring of benign prostatic hypertrophy, the patient must be under ongoing medical supervision during treatment.

Taking this medicinal product on empty stomach may cause nausea.

4.5 Interactions with other medicinal products and other forms of interaction

The results of in vitro studies showed the lack of inhibition potential of the lipido-sterolic extract of Serenoa repens

4.6 Fertility, Pregnancy and breastfeeding

Not applicable, as this medicinal product is not indicated in women.

4.7 Effects on ability to drive and use machines

Effects on the ability to drive and use machines have not been studied.

4.8 Undesirable effects

The following table shows the undesirable effects observed in 7 clinical studies on 3,595 patients in total, 2,127 of which were taking Permixon, for which the assessment of causality was not “excluded”.

The undesirable effects are presented according to the MedDRA system organ class and listed below as very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000) and unknown (cannot be estimated on the basis of available data).

The analysis showed no rare, very rare or very common undesirable effect. Thus, these frequencies are not represented in the table.

Common >=1% to 10%	**Uncommon >=0.1% to 1%**	**Unknown**
08-Nervous system disorders		
Headaches		
14-Gastrointestinal disorders		
Abdominal pain	Nausea	
15-Hepatobiliary disorders		
	An increase in Gamma-glutamyltransferase	
	an increase in transaminases	
16-Skin and subcutaneous tissue disorders		
	Rash	Oedema
20-Reproductive system and breast disorders		
	Gynaecomastia	

During clinical trials, only moderate increases in transaminases was observed and the increase in liver enzymes was of no clinical significance.

The cases of gynaecomastia observed were reversible after treatment discontinuation.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form at http://sideeffects.health.gov.il
In addition, you can report to Perrigo via the following address: www.perrigo-pharma.co.il

4.9 Overdosage

In the event of overdose, gastrointestinal disorders may occur.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Medicinal product used in Benign Prostatic Hypertrophy, ATC code: G04CX02. (G: Genito-urinary system and sex hormones)

:
Experimental work (conducted in animals or *in vitro* on prostate cells) and clinical studies (conducted in patients with benign prostatic hypertrophy) have shown that the lipido-sterolic extract of *Serenoa repens*:

- exhibits non-competitive inhibition properties on 5 α-reductase (type 1 and 2), an enzyme that transforms testosterone into its active metabolite, dihydrotestosterone;
- inhibits the formation of prostaglandins and leukotrienes (demonstrated on polynuclear cells);
- halts the proliferation of cells arising from benign prostatic hypertrophy, and stimulated by growth factors.

Its action on the arachidonic acid cascade and the effect observed on certain inflammatory cytokines explain the anti-inflammatory activity observed in both animal models and in benign prostatic hypertrophy.

5.2 Pharmacokinetic properties

It is impossible to fully evaluate the pharmacokinetic properties of medicines of this type as it is impossible to determine the concentrations of all plant extract components in the blood.

5.3 Preclinical safety data

Non-clinical data from conventional safety pharmacology, repeat dose toxicity, genetic toxicity and reproductive function and development studies reveal no particular risk for humans

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyethylene glycol 10,000, Titanium dioxide E171, Yellow iron oxide E172, Indigotin E132, Gelatin,

6.2 Incompatibilities

Not applicable.

6.3 Shelf-Life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25◦C

6.5 Nature and content of container

Box of 30, 56, 60 or 100 capsules in blister packs (PVC-Aluminum).
Not all packages may be marketed.

6.6 Special precautions for disposal and other handling

Not applicable.

7. MANUFACTURER
PIERRE FABRE MEDICAMENT
45 Place Abel Gance, 92100Boulogne, France

8. LICENSE HOLDER
Perrigo Israel Agencies Ltd., 1 Harakefet St., Shoham

9. REGISTRATION NUMBER
113-18-28916

10. DATE OF REVISION OF THE TEXT
Revised on 06.2021 according to MOH guidelines.

06.2021